

William L. Mentlik (WM 1540)
Arnold H. Krumholz (AK 2644)
Paul H. Kochanski (PK 0817)
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, NJ 07090-1497
Tel: 908.654.5000
Fax: 908.654.7866

Attorneys for Defendant IVAX Pharmaceuticals, Inc.

Document Filed Electronically

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ASTRAZENECA LP and	:	
ASTRAZENECA AB,	:	Civil Action No. 05-5142 (JBS) (AMD)
	:	
Plaintiffs,	:	District Judge Jerome B. Simandle
	:	Magistrate Judge Ann Marie Donio
v.	:	
	:	
IVAX PHARMACEUTICALS, INC.,	:	
	:	
Defendant.	:	
	x	

AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIM

Defendant IVAX Pharmaceuticals, Inc. by its attorneys, as for its amended answer to the Amended Complaint of AstraZeneca LP and AstraZeneca AB (collectively "AstraZeneca") states as follows:

JURISDICTION AND VENUE

1. Defendant admits the allegations of paragraph 1 of the Complaint.
2. Defendant admits that this Court has jurisdiction over the subject matter of the action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and further admits that this Court has personal

jurisdiction over the defendant under N.J. Ct. R. 4:4-4; as to the remaining allegations of paragraph 2 of the Complaint, defendant denies the same.

3. Defendant admits the allegations of paragraph 3 of the Complaint.

4. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 4 of the Complaint; and therefore, denies the same.

5. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 5 of the Complaint; and therefore, denies the same.

6. Defendant admits that AstraZeneca LP is the holder of the approved NDA No. 020-929 for budesonide inhalation suspensions 0.25mg and 0.5mg/2ml, respectively, and that the drug product is sold in the United States under the trade name PULMICORT RESPULES® (budesonide inhalation suspension); as to the remaining allegations of paragraph 6, defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the same.

7. Defendant admits the allegations of paragraph 7 of the Complaint.

8. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 8 of the Complaint; and therefore denies the same.

A. Defendant admits that United States Patent No. 6,598,603 (a copy of which is attached to the Complaint as Exhibit B) entitled "METHOD FOR TREATING RESPIRATORY DISEASES" issued on July 29, 2003, naming Bertil Andersson, Thor-Bjorn Conradsson, and Goran Eriksson as the inventors; as to the remaining allegations of paragraph 8B of the Complaint, defendant denies the same.

B. Defendant admits that United States Patent No. 6,899,099 (a copy of which is attached to the Complaint as Exhibit C) entitled "METHOD FOR TREATING A RESPIRATORY DISEASE" issued on May 31, 2005, naming Bertil Andersson, Thor-Bjorn Conradsson and Goran Ericksson as the inventors; as to the remaining allegations of paragraph 8C of the Complaint, defendant denies the same.

9. Defendant admits the allegations of paragraph 9 of the Complaint.

10. Defendant denies the allegations of paragraph 10 of the Complaint.

11. Defendant admits that IVAX Pharmaceuticals, Inc.'s ANDA No. 77-519 contains information to show that budesonide inhalation suspension 0.25 mg and 0.5 mg/2 ml (a) is bioequivalent to PULMICORT RESPULES®, (b) has the same active ingredient as PULMICORT RESPULES®, and (c) has the same route of administration, dosage form, or strength as PULMICORT RESPULES®; as to the remaining allegations of paragraph 11 of the Complaint, defendant denies the same.

12. Defendant admits that on September 14, 2005, in a letter addressed to AstraZeneca LP and AstraZeneca AB, defendant sent a "notification pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (codified as 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95)"; as to when AstraZeneca received the ANDA notice, defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegation, and therefore denies the same; as to the remaining allegations of paragraph 12 of the Complaint, defendant denies the same.

13. Defendant admits that the filing of ANDA No. 77-519, is an artificial act pursuant to 35 U.S.C. § 271(e)(2)(A) for the very limited and technical purpose of establishing

jurisdiction only; as to the remaining allegations of paragraph 13 of the Complaint, defendant denies the same.

14. Defendant denies the allegations of paragraph 14 of the Complaint.

15. Defendant denies the allegations of paragraph 15 of the Complaint.

16. Defendant denies the allegations of paragraph 16 of the Complaint.

AFFIRMATIVE DEFENSES

17. The commercial manufacture, use, or sale of budesonide inhalation suspension, for which defendant IVAX Pharmaceuticals, Inc. seeks approval in its ANDA No. 77-519, will not infringe any valid claim of U.S. Patent Nos. 6,598,603 and 6,899,099; and accordingly, defendant has not infringed U.S. Patent Nos. 6,598,603 and 6,899,099 pursuant to 35 U.S.C. § 271(e)(2)(A).

18. The claims of U.S. Patent Nos. 6,598,603 and 6,899,099 are invalid for failure to comply with the requirements of the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

19. Plaintiffs fail to state a claim as to infringement with respect to U.S. Patent No. 6,598,603.

COUNTERCLAIM

As for its counterclaim, defendant IVAX Pharmaceuticals, Inc. alleges as follows:

20. This counterclaim arises under the Patent Laws of the United States 35 U.S.C. §§ 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

21. Counterclaim plaintiff IVAX Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Florida, having its principal place of business at 4400 Biscayne Boulevard, Miami, Florida 33137.

22. Upon information and belief, counterclaim defendant AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at S 151 85 Sdertalge, Sweden.

23. Upon information and belief, counterclaim defendant AstraZeneca LP is a limited partnership organized and existing under the laws of the State of Delaware having its principal place of business at 1800 Concord Pike, Wilmington, Delaware.

24. Prior to the filing of this action, counterclaim defendants listed and/or cause to be listed U.S. Patent Nos. 6,598,603 and 6,899,099 for PULMICORT RESPULES® (budesonide inhalation suspension) in the publication of the Federal Food and Drug Administration ("FDA") entitled *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").

25. Counterclaim plaintiff IVAX Pharmaceuticals, Inc. has filed an Abbreviated New Drug Application (ANDA No. 77-519) pursuant to 21 U.S.C. § 505(j) seeking to obtain approval to engage in the commercial manufacture, use, and sale of budesonide inhalation suspensions.

26. Counterclaim plaintiff IVAX Pharmaceuticals, Inc. has submitted to the FDA a "paragraph IV" certification to the effect that no valid claim of U.S. Patent No. 6,899,099 will be infringed upon the manufacture, use, and sale of budesonide inhalation suspensions and with respect to U.S. Patent No. 6,598,603, certification has been made to the FDA as called for by § 355(j)(2)(A)(viii) of the Act that IVAX Pharmaceuticals, Inc. is not seeking approval for the method of use claimed in such patent.

27. By letter dated September 14, 2005, counterclaim plaintiff IVAX Pharmaceuticals, Inc. provided counterclaim defendants with the factual and legal basis for

counterclaim plaintiff IVAX Pharmaceuticals, Inc.'s contentions concerning the validity and/or noninfringement of U.S. Patent Nos. 6,598,603 and 6,899,099.

28. On October 26, 2005, counterclaim defendants commenced this action asserting infringement of U.S. Patent Nos. 6,598,603 and 6,899,099.

29. By virtue of counterclaim defendants having listed U.S. Patent Nos. 6,598,603 and 6,899,099 in the Orange Book and by virtue of counterclaim plaintiff IVAX Pharmaceuticals, Inc.'s submission of a paragraph IV certification regarding U.S. Patent No. 6,899,099 and a certification pursuant to § 355(j)(2)(A)(viii) as to U.S. Patent No. 6,598,603, and by virtue of the complaint filed herein by counterclaim defendants, an actual and justiciable controversy exists between counterclaim plaintiff and counterclaim defendants as to the validity and/or infringement of U.S. Patent Nos. 6,598,603 and 6,899,099.

30. The claims of U.S. Patent Nos. 6,598,603 and 6,899,099 are invalid for failure to comply with the requirements of the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

31. Counterclaim plaintiff IVAX Pharmaceuticals, Inc. is not infringing and, if its ANDA is approved, will not infringe any valid claim of U.S. Patent Nos. 6,598,603 and 6,899,099.

PRAYER FOR RELIEF

WHEREFORE, counterclaim plaintiff IVAX Pharmaceuticals, Inc., prays for judgment in its favor and against counterclaim defendants as follows:

- A. Dismissal of the Complaint with prejudice;
- B. A declaration that IVAX Pharmaceuticals, Inc. has not, does not, and that IVAX Pharmaceuticals, Inc.'s continued pursuit of its ANDA for budesonide inhalation suspensions and commercial marketing for sale of its budesonide inhalation suspensions, will not infringe any valid claim of U.S. Patent Nos. 6,598,603 and 6,899,099.

- C. A declaration of this case as "exceptional" within the meaning of 35 U.S.C. § 287;
- D. An award to IVAX Pharmaceuticals, Inc. of all costs of the suit and reasonable attorney fees; and
- E. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
Attorneys for Defendant
IVAX Pharmaceuticals, Inc.

Dated: January 26, 2006

By: s/ William L. Mentlik
William L. Mentlik